K113683

LIFESHIELD™ VISION™ Pre-Pierced Reseal Modification
Special 510(k)
Date: December 14, 2011

JAN 12 2012

Section 6: 510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92. LIFESHIELD™ VISION™ Infusion sets with Pre-pierced Reseal modification.

Submitter Information	
Name	Hospira, Incorporated
Address	D-393, Bldg. H2 275 North Field Drive Lake Forest, IL. 60046
Phone number	(224) 212-5316
Fax number	224-212-5401
Establishment Registration Number	Owner/Operator #9063339
Name of contact person	Karen Keener
Date prepared	December 14, 2011
Name of device	
Trade or proprietary name	LIFESHIELD™ VISION™ Infusion sets with Pre-pierced Reseal Access Port
Common or usual name	Fluid Delivery Tubing
Classification name	Infusion Sets
Classification panel	Class II
Regulation	21-CFR Part 880.5440
Product Code(s)	80-FPA
Legally marketed device(s) to which equivalence is claimed	K941214 LIFESHIELD™ Extension Set 10/03/1994 K052722 LIFESHIELD™ Latex Free Microbore Extension Set 11/02/2005 K101677 Hospira Infusion Blood Sets 08/11/2010
	The changes addressed in this submission include: • Material change of the pre-pierced housing access port from an acrylic multipolymer to polycarbonate • Addition of a Septum Holder using a medical grade material • Minor Dimensional change to the pre-pierced access ports • Use of BD plastic blunt cannula for port access
Device description	The LIFESHIELD™ VISION™ infusion sets, are intended for use as gravity sets or with dedicated Hospira Infusion Pumps. These devices are obtainable in custom lengths and component options according to facility needs and physician preference, Hospira infusion sets are disposable devices for single patient use, which incorporate various set configurations and components. The components include Pre-pierced access ports (Pre-pierced Male Adapter Plug, Pre-pierced Y-site, and Pre-pierced T-connector) which are the subject of this submission, may be shared across Hospira set families, may be used with sets for

Section 6: 510(k) SUMMARY

	gravity or other pump platforms.
Intended use of the device	Infusion sets are intended for the delivery of fluids including but not limited to blood and blood products from a container into a patient's vascular system.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	Proposed Device	Predicate
Intended Use	Same	Same
Set Functionality	Same	Same
Visual characteristics	Colorless polycarbonate of similar size	Green Acrylic Multipolymer
	white septum holder	Does not contain septum holder.
Bonding processes	Same	Same
Biocompatibility	Same	Same
Principle of Operation	Same	Same
Port Access	Plastic Blunt Cannula and needles ≤18guage	Metal Cannula and needles

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE*

Performance Test Summary-New Device

Characteristic	Standard/Test Method	Standard / Test T□tle	Device Performance
Biocompatibility	ISO 10993-5: 2009	Cytotoxicity	Pass
Biocompatibility	ISO 10993-10: 2010	Sensitization	Pass
Biocompatibility	ISO 10993-10: 2010	Irritation / Intracutaneous Reactivity	Pass
Biocompatibility	ISO 10993-11:2006	Systemic Toxicity (Acute)	Pass
Biocompatibility	ISO 10993-4:2006	Hemocompatibility	Pass
SAL 10^{-6}	ISO 11137-2:2006	Sterility	Pass
Dimensional conformance and Connection compatibility	ISO 594-2 1998	Conical fittings with a 6% (LUER) taper for syringes, needles and certain other equipment	Pass

Summary discussion of Bench Performance Data

The LIFESHIELD™ VISION™ Infusion sets with Pre-pierced reseal access ports have passed all specified test requirements.

The validation and verification testing have confirmed these devices meet user needs and design inputs for an infusion set.

Testing also confirmed physical attributes and device performance meet requirements of the standards listed in the "Performance Test Summary-New Devices" table above. These standards address sterility, biocompatibility, particulate, leakage, tensile strength, and filter characteristics.

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CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
Statement of Safety and Efficacy: The LIFESHIELD™ VISION™ Infusion sets with pre-pierced reseal access port meet the functional claims, and intended use as described in the product labeling. The safety and effectiveness, are substantially equivalent to the predicate Hospira Infusion sets cleared in K941214 LIFESHIELD™ Extension Set, K052722 LIFESHIELD™ Latex Free Microbore Extension Set and K101677 Hospira Infusion Blood Sets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Karen Keener
Senior Specialist
Hospira, Incorporated
375 N. Field Drive
Lake Forest, Illinois 60045

JAN 12 2012

Re: K113683
Trade/Device Name: LIFESHIELD™ VISION™ Infusion sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 14, 2011
Received: December 15, 2011

Dear Ms. Keener:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5: Indications for Use

510(k) Number (unknown at this time) K113683

Device Name: LIFESHIELD™ VISION™ Infusion sets

Indications for Use:

LIFESHIELD™ VISION™ Infusion sets are intended for the delivery of fluids including but not limited to blood and blood products from a container into a patients vascular system.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

1/9/12
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113683